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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,274	05/18/2001	Sulayman D. Dib-Hajj	2006636-0050	5193

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EXAMINER	
PAK, MICHAEL D	

ART UNIT	PAPER NUMBER
1646	

NOTIFICATION DATE	DELIVERY MODE
12/29/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@choate.com

Office Action Summary	Application No.	Applicant(s)	
	09/856,274	DIB-HAJJ ET AL.	
	Examiner	Art Unit	
	Michael Pak	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,22-31,35,36 and 40-44* is/are pending in the application.

4a) Of the above claim(s) *32-33, 37-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,22-31,35,36 and 40-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 20, 22-31, 35-36, and 40-44 are examined below.

2. Applicant's arguments filed September 17, 2007, have been fully considered but they are not found persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 20-31, 34-36 and 40-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (WO 93/06116) in view of Williams (US 5,731,284), Yan et al. (US 5,641,749) , Mayer et al. (US 5,352,683) and Holstege et al.(Neuroreport, 1998).

Lin et al. teach treatment by administering GDNF for variety of nerve damage including diabetes and Parkinson's disease (pages 3-4, 37-42 and 106-109). The GDNF administration inherently affects sodium channel. The treatment with GDNF inherently alleviate the pain. The GDNF administration inherently affect the sodium channel current flow or expression. The administered GDNF of Lin et al. will inherently affect the dorsal root ganglia or trigeminal neurons which are present in the administered animal or person. The sodium channels in the administered mammal inherently binds the lectin. Lin et al. does not teach a method which teach a specific dosages of GDNF. Lin et al. does not teach a method which teaches that the patient which is suffering from pain.

Williams teaches the method of administering GDNF in an amount effective to treat neural injury (columns 16-18). Williams teach that GDNF is useful for the treatment of nerve damage and recites Alzheimer's disease as a cause of nerve damage.(column 5, line 10). Furthermore, Williams teaches that neurotrophic factors are useful for treating the degeneration of nerve cells and loss of differentiated function that results from many different types of nerve damage including physical injury, damage due to ischemia, neurotoxins, neuropathy due to chronic metabolic diseases such as diabetes, and neurodegenerative diseases such as Parkinson's, Alzheimer's diseases and Amyotrophic Lateral Sclerosis (column 1, lines 12-33). Williams teaches the dosage of 10 ug/kg (column 6, lines 46-50).

Yan et al. teach the treatment of retinal ganglion cell injury such as glaucoma, physical injury, ischemia, neurotoxin, metabolic diseases such as diabetes, and neurodegerative diseases such as Parkinson's using GDNF (columns 1-5,14-20 and 25-6). Yan et al. teach that glaucoma can be characterized by painful eye (column 3, line 39). Yan et al. disclose the dosage of 1 ug/kg/day of GDNF administration (columns 4-5).

Mayer et al. teach that neuropathic pain is due to damage to peripheral nerves or to central nervous system (column 1). Mayer et al. teach that metabolic disorders such as diabetes may be related to abnormal functioning of the pain related regions of the nervous system (column 1).

Holstege et al. teach that presence of GDNF in the superficial dorsal horn may indicate that GDNF has role in nociceptive input and may be a neuromodulator of pain transmission (page 2897, second column, last paragraph).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Lin et al. by treating the a human suffering from pain as taught by Williams (US 5,731,284), Yan et al. (US 5,641,749) , Mayer et al. (US 5,352,683) and Holstege et al.(Neuroreport, 1998). One of ordinary skill in the art would have been motivated because Holstege et al. teach that GDNF plays a role in pain transmission. Williams, Yan et al., Mayer et al., and Lin et al. teach that nerve damage due to diabetes includes neuropathic pain and Holstege et al. leads one of ordinary skill in the art to the role of GDNF treatment of pain in human suffering from diabetes.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Lin et al. to incorporate the specific dosages of GDNF as taught by Williams et al. and Mayer et al. One of ordinary skill in the art would have been motivated because Williams et al. and Mayer et al. are analogous art which teach methods of adminstering GDNF for treatment of neural damages.

Applicants argue that in order for Lin et al. to meet the claim limitation that Lin et al. must necessarily include administration of GDNF to a subject suffering from pain. Applicants argue that the other references are deficient for the same reason. However, Mayer et al. clearly establishes that many of the neuropathy or nerve damaged patients suffer from pain. It is then clear that some or most of the neuropathic or nerve damaged patients suffer from pain. In administering GDNF to patients suffering from neuropathy and nerve damage, many of the patients suffering from pain will be treated by GDNF. Thus, the rejection does not assume that all patients administered GDNF have pain but some of the patients do because of Mayer et al. reference. Thus, the rejection is a 35 USC 103 obviousness rejection because some of the patients are suffering from pain when GDNF is administered.

4. No claims are allowed.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached from 8:30 to 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael Pak/
Primary Examiner, Art Unit 1646
18 December 2008